

3.0 SCHEDULES OF EVENTS

3.1 VACCINE

Day of Study	424	201	-12	1	7	10	17	24	31	38	45	
Week of Study	30	3	3	1	2	3	4	5	6	7	8	9
Month of Study												
History	X											
Initial Consent	X											
Biidrive		X										
Cytology/biopsies			X									
BBC				X	X	X	X	X	X	X	X	X
Vaccine				X	X	X	X	X	X	X	X	X
Historical/Physical Exam				X	X	X	X	X	X	X	X	X
Vital Signs				X	X	X	X	X	X	X	X	X
Performance Status				X	X	X	X	X	X	X	X	X
Routine Labs				X	X	X	X	X	X	X	X	X
Immunotherapy				X								
Chest X-Ray							X		X			*
CT Scan								X		X		*

† This can be extended up to -56 days only if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

* History/Physical Exam, Vital Signs, Performance Status, Routine Labs, Chest X-Ray q2 months in year 2, q3 months in year 3, then q6 months through year 5; CT or MRI at 18, 24, and 36 months (chest x-ray omitted if CT/MRI scheduled)

XA 0.1 mL of a 1:10 dilution of Tice BCG (Tice-A) mixed with vaccine

XB 0.1 mL of a 1:100 dilution of Tice BCG (Tice-B) mixed with vaccine

XC 0.1 mL of a 1:1000 dilution of Tice BCG (Tice-C) mixed with vaccine

This can be extended up to -34 days if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

†# Routine Labs: hematology (CBC with differential, platelet count), BUN or creatinine, LDH, SGOT, alkaline phosphatase, electrolytes

Xe End of Treatment Month

Figure 1